ADVERSE EVENT REPORT

I. EVENT INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			INDICATE ALL PPROPRIATE TO ADVERSE EVENT ☐ PATIENT DIED ☐ INVOLVED OR PROLONGED HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE-THREATENING ☐ CONGENITAL ANOMALY ☐ OTHER MEDICALLY IMPORTANT CONDITION
		Day	Month	Year	Years		Day	Month	Year	
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)										

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐YES ☐NO ☐UK ☐NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRO- DUCTION? ☐YES ☐NO ☐UK ☐NA
17. INDICATION(S) FOR USE		

18. THERAPY DATES (from/to)	19. THERAPY DURATION

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnoses, allergies, pregnancy with last menstrual period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF THE COMPANY MANAGING THE CASE		24b ORIGINAL REPORT N$^{O.}$
24c. DATE OF RECEIPT	24d DATE OF THIS REPORT	25a. REPORT TYPE ☐INITIAL ☐FOLLOW-UP
25b. REPORT SOURCE ☐STUDY ☐CONSUMER REPORT ☐LITERATURE ☐ OTHER ☐HEALTH PROFESSIONAL ☐REGULATORY AUTHORITY		26. NAME AND ADRESS OF REPORTER (Include Zip Code)